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| 10/587,542 | 07/28/2006 | Ooi Kiang Tan | P71388US0 | 9656 |
| 136 7590 09/15/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004 | | | EXAMINER LUM, LEON YUN BON | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/587,542

Applicant(s)

TAN ET AL.

Examiner

Leon Y. Lum

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 6-13, 15-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,163,659 to Stasiak *et al.* ("Stasiak") in view of U.S. Patent No. 5,922,537 to Ewart *et al.* ("Ewart").

i. Claims 1 and 15 are obvious

Stasiak teaches a capacitive sensor comprising two electrodes, one with a functional layer thereon and the other in contact with a sample such that the sample is between the two electrodes. See column 6, lines 52-65; column 12, lines 1-22; and Figure 7. The electrode with the functional layer comprises nanowires that are coated with a dielectric material, see column 3, lines 27-29 and column 4, lines 9-12, and can have immobilized biomolecules, such as antibodies, thereon, see column 8, lines 23-26. Stasiak also teaches a method of using the sensor, comprising introducing a sample

onto the sensor and placing a current or voltage through at least one of the electrodes, which necessarily polarizes an analyte attached thereto. See column 6, line 52 to column 7, line 18; and column 12, lines 40-43. Moreover, as would be recognized by one skilled in the art, the presence of two capacitor plates next to each other with the application of voltage would necessarily produce an electric field. Consequently, since a change in capacitance is detected, an electric field is necessarily and inherently established, and a device that can detect the change in capacitance is described.

Stasiak does not, however, teach a ferroelectric material on the transducer.

Ewart describes a method of optimizing a capacitive sensor device by including a dielectric made from ferroelectric ceramic, such as barium titanate. See column 14, lines 10-20.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Stasiak's method by incorporating Ewart's barium titanate as the dielectric layer. The skilled artisan would have been motivated to make the modification because Ewart indicates that the material can optimize the performance of a capacitive sensor. Using barium titanate as the dielectric would therefore optimize the performance of Stasiak's sensor. Moreover, since Stasiak's sensor is a capacitive sensor, the skilled artisan would have had a reasonable expectation of success in using barium titanate as the dielectric layer.

ii. Dependent claims 6-13, 16-19 and 21-24 are obvious

Regarding claims 6 and 7, Stasiak teaches the step of applying an electrical current to at least one of the electrodes. See column 6, lines 65-66. As would have

been apparent to one of ordinary skill in the art, capacitive sensing necessarily involves either applying a current and measuring a change in voltage or applying a voltage and measuring a change in current. Accordingly, it would have been obvious to perform either method using the sensor of Stasiak.

Regarding claims 8 and 17, Ewart teaches that the ferroelectric material can be a ferroelectric polymer. See column 15, lines 50-51.

Regarding claims 9 and 18, Ewart describes the ferroelectric layer is a thin film. See Figure 8. One of ordinary skill in the art would have found it obvious to transform Stasiak's nanowire arrangement into a thin film arrangement, because Stasiak and Ewart's sensors use the same components to perform the same function - i.e., dielectric-immobilized electrode having a biomolecule attached thereto for capacitive sensing. Indeed, the only differences between Ewart and Stasiak are the arrangement of the electrodes to each other and the structure of the dielectric layer. However, these elements are used in the same manner and, absent evidence to the contrary, can therefore be considered as interchangeable elements.

Regarding claims 10 and 19, Stasiak teaches that the analyte can be a protein. See column 4, line 22.

Regarding claims 11, 13, 22 and 24, since the sensor can have an antibody attached thereto for detecting an analyte, the antibody is considered a "probe" molecule and the analyte is attached directly to the transducer. See *supra* rejection of claim 1.

Regarding claims 12 and 21, the antibody can be attached onto the dielectric layer. See column 8, lines 48-55; Figure 2.

Regarding claim 16, since the electrodes have stored charge for performing capacitive detection, a voltage source is necessarily provided.

Regarding claim 23, Stasiak indicates that the analyte need not attach to the transducer through a biomolecule. See Figure 2.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stasiak in view of Ewart.

Stasiak and Ewart do not teach explicitly teach a step of determining a signal difference between an electric response and a reference signal.

Ewart does, however, describe a sensor in which one embodiment comprises a dual-sided device with the same layers on each side. See column 16, lines 20-37. The purpose of having a dual-sided device is to be able to conduct a reference test. See column 16, lines 38-39.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Stasiak and Alexander's method to include a step of comparing the sample and reference signals using Ewart's device. Indeed, there is but one purpose for performing reference test as described above – i.e., to determine a more accurate sample reading, which can only be accomplished by determining a difference between the sample and reference signals. Since the modification would simply involve running another test on a distinct portion of the sensor, the skilled artisan would have had a reasonable expectation of success in applying Ewart's technique to Stasiak and Alexander's method.

Regarding claim 3, Ewart evidences analyte detection through changes in electrical signal. Implicit in this description is the correlation between signal level and analyte concentration. Accordingly, Ewart inherently teaches that the signal is indicative of analyte concentration.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stasiak in view of Ewart as applied to claims 1 and 11-12 above, and further in view of Pankratz (US 4,810,639).

Stasiak and Ewart, described above, do not teach the step of "removing a remaining portion of said sample," as claimed.

Pankratz teaches a washing step to remove sample constituents and contaminants not bound to the solid phase. See column 8, lines 41-45.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Stasiak and Ewart's method by including a washing step to remove unbound analytes, as taught by Pankratz. The skilled artisan would have been motivated to perform the modification based on Pankratz's teaching that the washing step removes contaminants. Indeed, this step would prevent any interference by the contaminants in affecting the assay result. Moreover, Pankratz's washing step is provided in the form of an immunoassay, which is within the scope of Stasiak and Ewart's assay. Accordingly, the skilled artisan would have had a reasonable expectation of success in combining Pankratz's step with Stasiak and Ewart's method.

Response to Arguments

Applicants traverse the prior art rejections of the pending claims. See Response, pages 7-10. In particular, Applicants argue that Ewart does not anticipate the claims as amended, see pages 7-9, and that Stasiak in view of Alexander and in light of Ewart do not render the claims obvious, see page 9. With respect to Ewart, Applicants' argument is moot because the anticipation rejection has been withdrawn. In addition, Stasiak has now been combined with Ewart in a new rejection. Although, this rejection has not been considered by Applicants on the merits, Applicants' arguments against Stasiak, Alexander and Ewart are relevant and are addressed below. See page 9, last paragraph.

Applicants opine that neither Stasiak nor Ewart teach the functionality of the claimed sensor. *Id.* However, as described above, Stasiak and Ewart combined teach each and every element of the claimed method and device. Accordingly, the combination necessarily teaches any functionality associated with the claimed invention. Applicants also argue that Stasiak and Ewart do not teach the newly added limitation of a first electrode in contact with the transducer and the second electrode in contact with the sample only. *Id.* On the contrary, Stasiak describes this very limitation, in which one electrode is in contact with the biomolecule and dielectric-layered nanowire and another electrode is in solution. See Figures 2 and 7. Accordingly, Stasiak teaches the claimed first and second electrode.

In light of the foregoing statements, Applicants' arguments are not convincing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

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/Nelson Yang/

Primary Examiner, Art Unit 1641